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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,391	02/06/2004	John D. Norton	P11581.00	6350

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,391

Applicant(s)

NORTON ET AL.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-23 is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-12, 16, 24-26 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 7-9, 13-15, 27-30 and 34-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/14/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of applicant's amendment, which was received by the Office on September 19, 2006.

2. Claims 1-37 are active and pending.

Information Disclosure Statement

3. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on August 1, 2006.

Specification

4. In view of the applicant's submission of a new Abstract, the Examiner is withdrawing the objection, which was made against the specification in the last Office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the statement "to deliver the cardiac on a scheduled basis" (lines 2-3 of both claims) does not make any sense.

Claim Rejections - 35 USC § 102/103

7. Upon further reconsideration of applicant's arguments and amendments to the claims, the Examiner is withdrawing the 35 U.S.C 102(b)/103(a) rejection of Graham, Jr. (US 4,568,869), which was made against claim 16 in the last Office action.

8. Applicant's arguments with respect to claim 16 have been considered but are moot in view of the new ground(s) of rejection.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 5, 6, 10-12, 16, 24, and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al (US 5,904,705).

The Kroll et al (US 5,904,705) patent describes an automatic battery-maintaining implantable cardioverter defibrillator (ICD) and method for its use. Applicant's attention is directed to Fig.5, which shows a battery 13 with electrode terminals (cathode and anode -- not labeled), a "low deformation-rate capacitor" 30, and a "means for discharging" energy from the battery comprising switch 18. According to Kroll et al, over time, a battery may develop a detrimental film known as an "Equivalent Series Resistance" (ESR) (col.1, lines 24-56). To prevent build up of ESR periodic capacitor charging, or "reforming", is necessary (col.3, lines

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52-61). This “reforming” is currently periodic but may become unnecessary as fabrication of capacitors improves. Kroll et al suggests a discharge time of between 2-4 months (col.4, lines 41-44 and col.6, lines 65-67).

In regard to claims 5, 6, 11, and 12, applicant’s attention is directed to box 90 of the flow chart of Figs.10 and 11, which shows that the Kroll et al ICD is equipped with circuits capable of determining whether or not therapy was delivered to the patient within a 2-month period of time and if the therapy delivered was greater than 8 joules.

In regard to claim 10, electrodes 35 (Fig.5) are considered to be on the distal ends of stimulation leads attached to the patient’s body.

In regard to claim 16, the Kroll et al device includes circuits for sensing battery voltage potentials, which are indicative of film buildup. See the circuits of Fig.8 and 9.

In regard to claims 24 and 31, applicant’s attention is directed to Figs.10 and 11, which show an algorithm that determines whether or not therapy was delivered to the patient within a two month period of time (block 90). If not (“NO”), the algorithm ends and normal ICD operation resumes (“STOP”). If it has been more than 2 months (“YES”) since patient therapy has been delivered, then battery loading cycle 96 commences, which charges the capacitor (col.6, lines 35-37). This capacitor will continue to charge with a finite amount of energy for 2 seconds (block 100) or until a particular battery voltage is reached (i.e. $V > V_o - V_d$ – block 98).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2, 3, 4, 25, 26, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al (US 5,904,705) in view of KenKnight et al (US 6,112,117).

The Kroll et al (US 5,904,705) patent, described *supra*, recites most of applicant's claimed features but does not specify its own sensing and control circuitry for measuring patient cardiac signals and delivering shock therapy based upon the detected cardiac signals.

The KenKnight et al (US 6,112,117) patent describes a typical implantable cardioverter defibrillator (ICD) equipped with an endocardial lead system 16 (Fig.1) for both sensing cardiac signals which are processed by sensors 54 and 60 and analyzed for cardiac anomalies (i.e. morphology analyzer 62) and delivering appropriate shock therapy via circuits 64.

In regard to claims 26 and 33, the capacitors of the modified Kroll et al ICD are charged periodically every 2 months. See block 90 of Figs.10 and 11 of Kroll et al.

Allowable Subject Matter

13. Claims 7-9, 13-15, 27-30, and 34-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 17-23 are allowed.

Conclusion

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15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Kelly et al (US 2006/0051659 A1) patent describes techniques used to break up the formation of resistive coatings of sulfate ions on the terminals of lead acid batteries (paragraph [0005]). Unlike applicant's device, the battery of Kelly et al is not disclosed as being useful in an implantable medical device, nor does it include a positive recitation of a "low deformation-rate capacitor capable of storing a charge from the battery" in the manner claimed by the applicant.

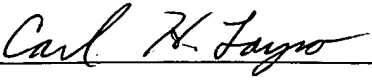
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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CARL LAYNO
PRIMARY EXAMINER

CHL
11/6/2006